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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,693	12/05/2001	Ajay Bhatia	210121.515C2	1153

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,693	BHATIA ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11 and 13-20* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 13-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9,11 and 13-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed on 2/19/03 is acknowledged. Claims 10 and 12 have been cancelled. New Claims 19-20 have been added. Claims 1-9, 11, 13-20 are pending in the application.

Priority

2. This application is a continuation in part of 09/841,260, Which Claims Priority from Provisional Application 60219752 Which Claims Priority from Provisional Application 60198853 2000 under 35 U.S.C. 120 is acknowledged.

Drawings

3. No drawings have been submitted in this application.

Information Disclosure Statement

4. Information Disclosure Statements filed on 3/08/02, Paper # 6 is acknowledged and a signed copy is attached with this action.

Election

5. Applicant's election of GroupV claims 10-12 with respect to SEQ.ID.NO: 139 in Paper No 9, 2/19/03 without traverse is acknowledged. Claims 10 and 12 have been canceled and replaced with claims 19 and 20. Therefore, claims 19, 11 and 20 are under examination. Claims 1-9 and 13-18 are withdrawn from consideration.

Claim Rejections - 35 USC 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a first component selected from the group consisting of physiologically acceptable carriers and immunostimulant and a second component consisting of a polypeptide as set forth in SEQ.ID.NO: 139 does not reasonably provide enablement for a composition comprising a first component selected from the group consisting of physiologically acceptable carriers and immunostimulant and a second component consisting of a polypeptide having at least 95 % and 99% identity with the polypeptide sequence of SEQ.ID.NO: 139. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Scope of enablement requires that the specification teach those in the art how to make and use the invention commensurate with the scope of the claimed invention without undue experimentation and includes an analysis of: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those the art, and (8) the breadth of the claims.

With regard to %identity, the specification is not enabled for polypeptide which has at least having at least 95 % and 99% identity amino acid sequence identity with SEQ.ID.NO: 139 because it is unclear to one skilled in the art what sequences are embraced by the claim. If it is unclear to one skilled in the art what sequences are embraced by a claim which is based on a specification to determine percent identity, the specification is non-enabling, since one skilled in the art would not be able to make and use those sequences without undue experimentation.

Applicant has not set forth which amino acid (s) in the polypeptide SEQ.ID.NO 139 comprising 660 amino acids can be deleted or inserted or substituted to give rise to the polypeptide having at least 95 % and 99% identity with SEQ.ID.NO: 139. After these alterations or modifications whether the polypeptide can still retain the activity of stimulating T-cells is not set forth in the specification.

The specification provides guidance and direction with regard to an isolated polypeptide comprising 660 amino acids as set forth in the SEQ.ID.NO 139, which is designated as CT 622. However, the specification fails to teach a polypeptide comprising at least having at least 95 % and 99% identity amino acid sequence identity to SEQ.ID.NO 139 and it's use in a method for stimulating and/or expanding T-cells. It is well known that for proteins, for example, even a single amino acid change can destroy the function of the biomolecule. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Applicant failed to give direction to what modification have been done to SEQ.ID.NO 139 to give rise to having at least 95 % and 99% identity sequence identity to said polypeptide. What changes would have an adverse effect on the function of this peptide is not predictable. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid and sequences for different aspects of biological activity can not be predicted a priori and must be determined empirically on a case by case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6). The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the protein (Burgess et al., The Journal of Cell Biology,

111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology, 8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol., 1991, 5(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which products proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of structural components to both biological function and immunological recognition. Applicants have not taught which residues of SEQ ID NO: 139 can be varied and still achieve a protein that is functional in stimulating and/or expanding T-cells specific for Chlamydia protein. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

8. Claims19 and 11 (examiner is viewing the claim 11 as if it dependents from claim 19) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are drawn to a method for stimulating and/or expanding T-cells specific for a Chlamydia protein, comprising contacting T-cells with a composition comprising at least an immunogenic portion of a peptide selected from the group consisting of (a) the polypeptide of c (b) a polypeptide having at least 95 % identity with the polypeptide sequence of SEQ.ID.NO:

139(c) a polypeptide having at least 99%identity with the polypeptide sequence of SEQ.ID.NO: 139.

The nature of the disclosed invention is a method of stimulating and/or expanding T-cells specific for a Chlamydia protein. The method thus requiring the use of the Chalmydia polypeptide, i.e., SEQ.ID.NO: 139 and polypeptides having at least 95 % or 99% identity with the polypeptide sequence of SEQ.ID.NO: 139 in expanding T-cells specific for Chlamydia. The specification discloses that the recombinant full-length protein, SEQ.ID.NO: 139 is expressed in CT622 and has been shown to contain 660 amino acids. The specification fails to disclose the actual biological function of the polypeptide SEQ ID NO: 139. Further, the specification fails to teach a polypeptide having at least 95 % identity with the polypeptide sequence of SEQ.ID.NO: 139 and a polypeptide having at least 99%identity with the polypeptide. The specification, however, provides no working examples demonstrating (i.e., guidance) enablement for use of the claimed polypeptides in stimulating and/or expanding T-cells specific for a Chlamydia protein. The induction and expansion of specific T-cells to peptide epitopes from protein antigens is highly complex as taught by the prior art, Unanue. ER 1999 (see attached review article, American Journal of Pathology; 154; 651-664). It is apparent that the immunogenicity of T-cell epitopes has been particularly difficult to define because of the added complexity resulting from the need for a first step for processing, and peptide interaction with major histocompatibility molecules (MHC) proteins. Further, protein antigens must be handled by antigen presenting cells (APC) to be recognized by the T-cells (see page 651, left column, second paragraph through right column). Following a period of internalization by the macrophages, the T-cells were able to recognize products of bacteria, Listeria monocytogenes. However, chemical neutralization of proteolytic activity abolished the expansion of the T-cell epitopes (see page 652, left column, first paragraph). Thus interaction of T-cells and APC

appear to be complex with bacterial antigens or peptides. In view of the complex nature of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

Claim Rejections - 35 USC 112, second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 19-20 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is rejected as being vague for the recitation of " T-cells specific for a Chlamydia protein" because the claim does not recite that T-cells are contacted with a Chlamydia protein.

Claim 19 is rejected as being vague in reciting "at least an immunogenic portion ". It is not clear which portion of a polypeptide is immunogenic?

Claim 19 is rejected as being indefinite for the recitation of "and/or" because It is not clear how to stimulate and expand T-cells by contacting T-cells with a polypeptide?

. Claims 19 and 11are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP 2172.01.

Applicant claims a method for stimulating and /or expanding T-cells specific for a Chlamydia protein. . However, there is no step, which correlates contacting T-cells with a composition and stimulation and/or expansion of T-cells. At present, claim is drawn to only contacting T-cells with a composition. Further, there is no step for measuring stimulation and expansion of T-cells.

Claim 11 is objected to under 37CFR 1.75 as being improper dependent form as it depends from a canceled claim 10.

Status of Claims

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

3/18/03

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600